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13. ABSTRACT (Maximum 200  The Institute for Laboratory Animal Research (ILAR) is a component of the Commission on Life Sciences (CLS), National Research Council (NRC). Founded in 1952, ILAR has become recognized nationally and internationally as a leader in developing and making available to the biomedical and laboratory animal science communities guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of humane care and use of laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals. ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program, which is carried out by NRC-appointed committees with staff assistance. The number of committees and size of the staff are dependent on the number of special projects and available funding. Both programs are directed by a 14-member Council comprised of experts in laboratory animal medicine, zoology, genetics, medicine, ethics, and related biomedical sciences. The Army funds partially support general office operations, the Animal Models and Genetic Stocks Information Program, publication of <i>ILAR Journal</i> , and work of the Council.			
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## FOREWORD

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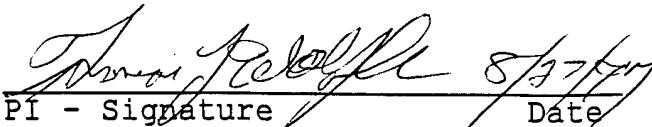
\_\_\_\_ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23; Revised 1985).

\_\_\_\_ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

\_\_\_\_ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

\_\_\_\_ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

\_\_\_\_ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

  
\_\_\_\_\_  
Dr. Donald P. Coffey  
\_\_\_\_\_  
PI - Signature      Date

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## INTRODUCTION

For the past five years the Army has provided partial core support to the Institute for Laboratory Animal Research (ILAR), a component of the National Research Council's (NRC) Commission on Life Sciences. The NRC is the operating arm of the National Academy of Sciences, a private, nonprofit organization that was created in 1863 by congressional charter to serve as an official advisor to the federal government on questions of science and technology.

Founded in 1952, ILAR has become recognized nationally and internationally as a leader in developing and making available to the biomedical and laboratory animal science communities guidelines for animal care, breeding, and use; descriptions of animal models for human diseases and physiological processes; and reports on specific issues of scientific and humane use of laboratory animals. These guidelines from the National Academy of Sciences serve as important indications to members of congress, government officials, the press, and the public of the high quality of care provided to laboratory animals. ILAR's mission is to help improve the availability, quality, care, and humane and scientifically valid use of laboratory animals.

ILAR's studies, like all those of the NRC, are carried out by recognized experts in fields appropriate to the required tasks. These serve on a volunteer basis, without compensation. As a part of the NRC, ILAR has access to this country's most knowledgeable and distinguished laboratory animal and biomedical scientists, who provide objective counsel on laboratory animal matters. A significant number of the experts used by ILAR are also members of the National Academy of Sciences or the Institute of Medicine. In some cases, ILAR utilizes scientists from other countries.

Reports of NRC studies are extensively reviewed by independent NRC-appointed experts in the subject area before they are released. They are prepared in sufficient quantity to ensure distribution to the sponsor, experts, and other relevant parties in accordance with Academy policy. Reports are usually made available to the public without restriction.

## ILAR'S GOALS

- Since its founding, ILAR has provided guidance and information on laboratory animal matters to the federal government, the biomedical and laboratory animal science communities, and the public. In keeping with its mission, ILAR continually seeks to strengthen and refine its existing programs and to initiate new programs that will assist government officials; scientists who use animals in research, testing, and education; and the institutional animal care and use committees that monitor animal use. During the period of the requested grant, ILAR's goals will be as follows:
  - to provide a forum within the National Academy of Sciences for the Department of Defense to discuss issues and develop guidance for laboratory animal-related matters;
  - to continue to serve on behalf of biomedical science and education as an authoritative voice within the U.S., and on behalf of the U.S. scientists internationally;

- to promote humane and appropriate care and use of laboratory animals;
- to provide scientific guidance on laboratory animal-related issues to agencies of the federal government and others on request;
- to provide information on laboratory animal matters to government officials, laboratory animal and other biomedical scientists, institutional animal care and use committees, and the public;
- to promote the use of standardized nomenclature for accurately defining and identifying genetic stocks of animals;
- to assist developing countries attain quality laboratory animal science programs through dissemination of information including the translation of ILAR reports;
- to promote cost-effective ways to preserve valuable animal models; and
- to broaden the access to information on selection of appropriate biological models and methods through ILAR's home page, databases, publications, and resources of the new ILAR Associateship program.

### Accomplishing The Goals

ILAR accomplishes its goals through its core program, which is carried out by the staff, and its special-project program. The number of studies and size of the staff are dependent on the number of special projects and available funding. Both programs are directed by a 14-member ILAR Council comprised of experts in laboratory animal medicine, virology, zoology, genetics, medicine, ethics, and related biomedical sciences.

## THE CORE PROGRAM

### ILAR Council

The ILAR Council (see addenda for roster) serves four principal functions: to provide program direction and strategic planning; to oversee the information programs, which consist of the Animal Models and Genetic Stocks Information Program and the quarterly *ILAR Journal*; to oversee special projects; and to direct ILAR's international programs and its participation as the U.S. national member in the International Council of Laboratory Animal Sciences (ICLAS). The international program is discussed in the Special Projects section below. Periodically, the Council meets with other scientists and funding agency administrators to discuss areas in which ILAR might prove useful. It then uses these discussions in strategic planning. The Council occasionally employs core funds to undertake specific, NRC-approved projects itself.

### Staff

ILAR is staffed by a director, a half-time managing editor of the *ILAR Journal*, a half-time project assistant who maintains the AMGS database, a project assistant and secretary to the director, and a

project director (currently vacant). Under the special projects program, staff works closely with experts to engage in studies, develop working papers, assist in the production of a cohesive report, and conduct literature reviews. The curricula vitae of the professional staff are furnished in the addenda.

#### **Animal Models and Genetic Stocks Information Program**

Some of the most critical information needed by Department of Defense scientists is often the most difficult to obtain, including information on the most appropriate model for the proposed research and, if the model is an animal, to find sources of the model and information on appropriate care. As author of the Guide for the Care and Use of Laboratory Animals, ILAR is in a position to assist investigators and Institutional Animal Care and Use Committees (IACUCs) in interpreting guidelines for the humane care and use of animals and fulfilling requirements of the Animal Welfare Regulations regarding reduction of pain and distress and identification of alternative methodologies. For over 40 years, ILAR has conducted a program to provide such information. That program, called the Animal Models and Genetic Stocks Information Program, offers assistance in locating sources of animals, selecting appropriate animal models, using standardized nomenclature, and understanding the importance of the use of animals in biomedical and behavioral research and testing. It includes two databases: one (called Animals for Research, AFR) contains commercially available and investigator-held colonies of animals for research; the other is a registry of codes used with standardized nomenclature of rodents and rabbits to identify institutions that maintain breeding colonies. During 1996 ILAR staff documents over 1,200 responds to questions and responded to many more by telephone, fax, and e-mail. The databases have been incorporated into ILAR's World Wide Web (WWW) home page and are available to investigators world-wide.

#### ***ILAR Journal***

With oversight and guidance by the ILAR Editorial Board, *ILAR News* was reformatted, and expanded, and renamed *ILAR Journal* in 1995. *ILAR Journal*, a quarterly, peer-reviewed publication, provides thoughtful and timely information for all those who use, care for, and oversee the use of laboratory animals. The audience of *ILAR Journal* includes more than 3,500 investigators in biomedical and related research, institutional officials for research, veterinarians, and members of animal care and use committees. The *ILAR Journal* Editorial Board, of the ILAR Council, plans each issue around a chosen theme and carefully solicits authors to best present a balanced view of the topic which is then peer reviewed.

An issue of special interest to those researchers using more sophisticated animal models in biological research is Unusual Mammalian Models (Volume 38, Number 1), which contains 5 papers describing a special animal model selected because of its uniqueness and relevance and explores some of the husbandry issues associated with it. The articles review the laboratory opossum (*Monodelphis domestica*), unusual rodent species, specific-pathogen-free nonhuman primate colonies, specific-pathogen-free pigs, and the use of transgenic technology in animal science. This issue also includes an article about the 1996 Guide for the Care and Use of Laboratory Animals prepared by members of the ILAR Committee to Revise the Guide.

The most recent issue, *The Role of Computational Models in Animal Research* (Volume 38, Number 2), acquaints readers with examples of modeling applications in fields related to biomedical and laboratory Animal Science. The issue covers metabolic models, demographic and population genetic models, statistical genetic methods, and the use of models in training and education. This issue also included a summary of the newly-released *Occupational Health and Safety in the Care and Use of Laboratory Animals*.

### ILAR Associate Program

In an effort to provide better access to ILAR's information and resources and to better leverage funding from core and project sponsors, ILAR has initiated an associateship program. The program has been advertised in recent editions of the *ILAR Journal*, in letters sent to *ILAR Journal* subscribers and research institutions and departments of comparative medicine and animal care, and through ILAR's exhibit and presentations at local and national scientific meetings. Individuals and institutions who subscribe to the associate program help defray the cost of publishing the *Journal* and managing the AMGS program. ILAR Associates receive the *ILAR Journal* (number of copies varies with level of Associate membership), expedited and individualized responses from the AMGS program, and will receive a 20% discount on all ILAR publications, as well as all publications of the National Academy Press. Subscribers will receive a yearly report of ILAR's activities, and a brief survey to provide input on the most important issues and concerns that ILAR should be addressing and how to provide the kinds of information needed. As do ILAR's core sponsors, the Associates arguably represent the best of U.S. biomedical and laboratory animal scientists and will serve as an important audience to receive, critique, and provide guidance to ILAR's programs. ILAR's core sponsors are valuable members of the Associates program.

### SPECIAL PROJECTS

Projects are developed in response to specific requests from government agencies and private organizations or on the initiative of staff, or ILAR Council. Although these projects are supported by contracts and grants from federal agencies, foundations, and private organizations, they are never completely separate from the core program because the Council is involved during each step of the process. This sponsorship provided by this grant is recognized in each published ILAR report. The Council reviews each project extensively before it is undertaken, examines, the qualifications of experts, oversees the conduct of the project to ensure that it is accomplished in a timely manner, and reviews and signs off on each report as a part of the NRC review process. In addition, ILAR reports are frequently published as special inserts of the core-support *ILAR Journal*. The following projects are examples of recently completed projects, or projects that are underway or which will begin when funding has been received.

### ICLAS and International Activities

ILAR has had a long history of interest in international laboratory animal science. Historically, this interest has sought to assist young investigators in developing countries through dissemination of reports (some translated into foreign languages to increase their usefulness) and participation in international meetings that support young investigators. In 1988, ILAR became the U.S. national member of the International Council for Laboratory Animal Science (ICLAS), with support from member agencies (including USAMRDC) of the Interagency Research Animal Committee (IRAC). This membership affords a conduit for U.S. investigators to develop and conduct an active international program in laboratory animal science. One goal of the U.S. membership in ICLAS was to streamline ICLAS management and programs to better represent U.S. scientists in the international community. In 1995, that goal came to fruition through the election of former ILAR Council chairman (Steven Pakes) as Secretary General of the ICLAS General Assembly. Dr. Pakes works closely with ILAR and is an annual guest of ILAR Council to discuss ICLAS and other international issues. One topic of mutual interest to both ILAR and ICLAS is the international biologic and genetic standardization of laboratory rodents. Upon publication of ILAR's Definition, Nomenclature, and Conservation of Rat Strains, ICLAS instituted regional laboratories on quality control with a goal of achieving these international standards.

ILAR interacts with numerous organization and agencies in the United States and foreign countries. Among these are the NRC/CLS joint programs with the Mexican Academy of Sciences, and the Pan American Health Organization, Fogarty International Center at NIH, Department of State, Centers for Disease Control and Prevention, Interagency Research Animal Committee, U.S. Agency for International Development, Canadian Council on Animal Care, Agriculture Canada, and various scientists and government officials in Asia and in Latin America and the Caribbean. In addition, ILAR maintains close contact with U.S. scientific societies, pharmaceutical companies, biomedical investigators, veterinarians, and administrators. This network serves to alert ILAR of existing or anticipated international problems affecting biomedical and biological research and biodiversity and to enable ILAR to better understand the broad needs of U.S. science in interacting with foreign organizations.

In recent years, ILAR has devoted increasing attention to the activities of the North American Free Trade Agreement (NAFTA) and the World Trade Organization as they evolve policies affecting scientific exchange. Two trilateral meetings with Canada, Mexico, and the U.S. were convened by the ILAR Council during the present grant. These organizational meetings served to discuss key issues that might impact the exchange of biological and pharmaceutical products and animals and to introduce key people in each country to those of the other countries. Such meetings serve a vital link in achieving seamless international trade and resolutions of trade problems, such as the exchange of biologicals and products among investigators in different countries. Meetings between the Administrator of the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture and the ILAR Director and members of the ILAR Council were held and promise to grant ILAR greater access to participation in development of U.S. policies in regard to biological sciences issues brought before the World Trade Organization. This, and increased attention to activities of the European Council and European national legislation affecting the use of laboratory animals will enable ILAR to retain its position in international laboratory animal science for the purpose of fostering biomedical science.

Upon publication of the 7th edition of the *Guide*, the National Academy Press received several requests for foreign language translations of the document. As evidence of the importance of this report internationally, this edition has been translated into Spanish, Chinese, Japanese, and Portuguese at no cost to ILAR. Translations into other languages have also been requested and will be encouraged. All translations are reviewed by ILAR-appointed reviewers with expertise in English, the new language, and with the content and "performance" tone and intent of the *Guide*. The use of the *Guide* internationally by scientists and laboratory animal personnel further supports ILAR's effort to achieve animal care and use policies that will facilitate international scientific exchange of biologicals and products. Without agreements on such issues of humane care and use of laboratory animals (part of the forthcoming "Green Round" of the WTO), this trade has often been delayed or prohibited in the past.

ILAR will continue to work in international areas in partnerships with US scientific enterprises to facilitate and foster acquisition and trade affecting biomedical science.

#### Laboratory Animal Management Reports

ILAR periodically revises or prepares new reports in its *Laboratory Animal Management Series*. This series provides species-specific information supplemental to that in the *Guide for the Care and Use of Laboratory Animals*<sup>3</sup>. Two reports have recently been completed in this series. A revision of ILAR's 1973 report *Dogs: Standards and Guidelines for the Breeding, Care, and Management of Laboratory Animals*, which was published by the National Academy Press under the new title *Dogs: Laboratory Animal Management Series*.<sup>4</sup> This report provides a detailed supplement to the *Guide* for the care, management, and use of this species, includes a discussion and recommendations regarding the Animal Welfare Regulation's requirement that institutions provide exercise for dogs, and includes a section on the unique veterinary and ethical issues surrounding the care and use of canine models of disease. Secondly, *Rodents: Laboratory Animal Management*, which provides an update of two earlier reports on laboratory Rodents, was recently published by the National Academy Press.<sup>5</sup> This report is especially timely in view of the discussions by the Department of Agriculture to include mice and rats as species regulated under the Animal Welfare Regulations. Funding is currently being sought to continue updating the Nonhuman Primate and Swine reports under the Laboratory Animal Management Series.

#### Standardized Nomenclature for Transgenic Animals

It is estimated that in excess of 10,000 unique strains of transgenic mice have been developed, with more being created weekly. In order for the biomedical community to utilize, maintain, and preserve these animals, a standardized nomenclature is essential. The ILAR Committee on Transgenic Nomenclature developed such a nomenclature during the early part of the present grant period and field tested it in the United States, Europe, and Japan. The report was published in *ILAR News*<sup>6</sup> and the nomenclature rules are adopted by the International Committee on Standardized Genetic Nomenclature for Mice and are incorporated in "T-Base," the Johns Hopkins University Transgenic Animal database.

## Definition, Nomenclature, and Conservation of Rat Strains

As genetically defined rat strains are being increasingly selected as research models, problems have arisen that can significantly affect research, including improper use of nomenclature; lack of criteria for ensuring genetic quality, sharing of strains, and preserving unique genetic stocks; and lack of communication between geneticists and other scientists who use rats. The Committee on Rat Nomenclature, comprised of U.S., European, and Japanese experts in rat genetics, is addressing these problems. As part of its report, they prepared rules for standardized nomenclature for rats, and recommended that a permanent body, under the auspices of an appropriate international organization, implement the nomenclature and address problems related to the use of genetically defined rats on an ongoing basis. The report was published in *ILAR News*<sup>7</sup> and its recommendations adopted by ICLAS.

## Psychological Well-Being of Nonhuman Primates

This project was initiated at the request of the Department of Agriculture to provide guidance to assist institutions and inspectors in developing and assessing institutional programs for the psychological well-being of nonhuman primates in research environments, as required by the Animal Welfare Regulations. This study will provide USDA Animal Welfare inspections, and both small and large research institutions housing primates, with starting points from which to develop their programs.

The report will recognize the approximately 40 species of primates in research, and greatly differing research agendas on which they are used, and seek to encourage thoughtful dialogue and creativity in achieving the goals of the Animal Welfare Regulations. The report is currently in review and is expected to be completed in late summer 1997.

## Occupational Safety and Health Programs for Personnel in Research Animal Facilities

The *Guide* requires institutions to have an occupational health and safety program, but references this report for implementation of such a program. This study comprehensively reviews safety and health concerns associated with animal facilities and recommends procedures by which federal laboratories and large and small institutions can appropriately address these concerns. The report<sup>8</sup>, for the first time, provides institutions conducting research with detailed recommendations for the components to include in an occupational health and safety program. The report was published by the National Academy Press in 1997.

## Revision of the *Guide*

The *Guide for the Care and Use of Laboratory Animals (Guide)* is, without question, the most widely used of ILAR's reports; more than 400,000 copies of its various editions have been distributed internationally. Compliance with its guidelines is required for Department of Defense and all other federal agency grantees and contractors that use animals in their research. Its tenets are also used by the American Association for Accreditation of Laboratory Animal Care in certifying animal care programs. This report revised the 1985 edition of the Guide in order to update the document to make the '96 Guide current in compliance areas, state-of-the art techniques and equipment, and science, and

use performance standards rather than engineering standards whenever appropriate. The purpose of the *Guide* is to assist institutions in developing and maintaining animal care and use programs that are scientifically, technically, and humanely appropriate and to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principles. The 7th edition was published in 1996 and has been translated into Spanish, Chinese, Japanese, and Portuguese with other translations expected.

### The Role of New and Emerging Models in Biomedical and Behavioral Research

Funding has been received from NIH to prepare a report that will examine opportunities and priorities for animal-based, scientifically driven research in the Comparative Medicine Program at the National Center for Research Resources. The workshop to be held in December 1997 will use case studies to discuss criteria and action needed to identify useful new animal models for biomedical and behavioral research; the tools, technologies, and resources needed to develop and support them; and the barriers that can prevent or delay their development and support. This workshop is to be held in December 1997.

### Chimpanzees in Research: Strategies for Their Ethical Care, Management, and Use

Due to their close phylogenetic relationship to humans, chimpanzee models have led to better understanding of human and animal diseases, development of important new vaccines, and behavioral knowledge essential to the conservation of the species. With funding from NIH, the NRC prepared a report that provides recommendations for the long-term care and appropriate use of chimpanzees that have served as valuable models in biomedical and behavioral research. The study assessed the importance of chimpanzees for future research and testing and to make recommendations on how best to manage current populations to meet critical needs. The report was completed in June 1997.

### Workshop Series on Access to Biologicals for Research and Education

ILAR has received partial funding for a series of meetings to assess the process by which U.S. federal agencies provide permits for the importation and exportation of animals and biologicals. Biological research increasingly requires the collection and movement of sera, cells, and other specimens as well as whole plants and animals from one country to another or from the field to a laboratory. Collection, transport and disposition of such material is closely regulated to protect both the species and its ecology and the public health. The resulting rules and regulations have become exceedingly complex. A workshop held in March 1994 concluded that further workshops would be helpful in understanding and finding ways to simplify the permitting process and harmonize the permitting process of the various agencies in the US. Additional meetings will be held when adequate funding is obtained.

### Implementing the Science Standards: the Appropriate Use of Animals and their Alternatives in Education

This study is being proposed as a three-day workshop during which invited science teachers and administrators, biologists, veterinarians, and other will define the objectives of animal use, examine proper treatment of animals by students and teachers. Two reports would be produced: a technical document that will reflect the workshop's discussions; a summary document for lay audiences, written by a popular science writer. Funding is being sought for this project.

### The Cost of Animal-Based Research

Many life scientists believe that the high and rising costs associated with animal research are adversely affecting research grants and unnecessarily limiting the pace of research. The basis for this concern was discussed at a workshop on June 10-11, 1997, which resulted in a request for a in-depth NRC study explore the true costs of biological research, including animal cost (actual and indirect), administrative costs (oversight committees, paper work, and regulatory requirements including permitting and transporting costs, Office of Management and Budget (OMB) Circular A-21 (which prohibits indirect costs for animal colonies), and other issues. By focusing on the costs associated with animal-based research, such a study would assist in the reduction of unnecessary administrative costs and would provide a clearer understanding to investigators of the basis for per diem costs. Recommendations for cost-reduction will be provided where possible. ILAR is seeking funding for this study.

### STATEMENT OF WORK

ILAR will continue to participate in the NRC mission by providing guidance to the Department of Defense, and to other government, national, and international scientific communities on issues of science and science policy relating to animal models and biological resources used in research, testing, and education. ILAR will also continue efforts to enhance federal and public support for the infrastructure of animal research and biological resource models. The following constitute the specific plan of action for the core program during the next 5 years:

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**ILAR/NRC Reports, 1992 - 1997**

*Definition, Nomenclature, and Conservation of Rat Strains.* 1992. A report of the Institute for Laboratory Animal Research Committee on Rat Nomenclature. ILAR News 34(4)1992. The report revised rules for standardized nomenclature for rats and endorsed the ILAR report *Important Laboratory Animal Resources: Selection Criteria and Funding Mechanisms for Their Preservation*, which lists criteria for evaluating animal resources and suggests mechanisms for preserving those of scientific value. Reprints are distributed by ILAR.

*Standardized Nomenclature for Transgenic Animals.* 1992. A report of the Institute for Laboratory Animal Resources Committee on Transgenic Nomenclature. ILAR News 34(4)1992. The report provides a nomenclature for transgenic animals and delineates a means by which the nomenclature can be used to create a catalog of existing transgenic resources.

*Dogs: Laboratory Animal Management.* 1994. A report of the Institute for Laboratory Animal Research Committee on Dogs. Washington, D.C.: National Academy Press. pp 138. The report covers selection of dogs as research models, design, construction, and maintenance of indoor and outdoor facilities, temperature, humidity, food, water, bedding, sanitation, animal identification, record keeping, and transportation, and general veterinary care, as well as special care of breeding animals and random-source animals.

*Guide for the Care and Use of Laboratory Animals, 7th Edition.* 1996. A report of the Institute for Laboratory Animal Research Committee to Revise the Guide for the Care and Use of Laboratory Animals. Washington, D.C.: National Academy Press. pp. 125. The purpose of the Guide is to assist institutions in caring for and using laboratory animals in ways judged to be professionally and humanely appropriate. It provides information on common laboratory animals housed under a variety of circumstances.

*Rodents: Laboratory Animal Management.* 1996. A report of the Institute for Laboratory Animal Research Committee on Rodents. pp. 167. Detailed recommendations are provided for the housing and care of rodents used in biomedical research, testing, and education. The report serves as a species-specific supplement to the Guide for Care and Use of Laboratory Animals.

*Chimpanzees in Research: Strategies for Their Ethical Care, Management and Use.* 1997. pp. 67. The report addresses the following issues: The size of the breeding colony required to support the need; issue of ownership, long-term care, and use in research; mechanisms by which nongovernment organizations could assist in achieving appropriate goals and solutions for the long-term care of chimpanzees.

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